SUBCOMMITTEE # 4 REPORT
Technology, interoperability, governance, policy, and legal issues in EHR

Draft # 3-- 10/25/05

Subcommittee Work Plan

Subcommittee #4 agreed to provide two deliverables to the Task Force: 1) a high-level technology plan which supports pilot projects that may be proposed by other Task Force subcommittees and 2) principles for the pilots which ensure privacy and security of electronic health records. The pilot infrastructure, in turn, would serve to support continued progress towards a more complete health information system throughout Virginia in the next 5-10 years. The subcommittee's two deliverables are contained in the Findings and Recommendations section below.

Summary of Subcommittee Meetings

Subcommittee #4 held meetings in July, August, and September 2005. Testimony taken and information provided at the meetings includes:

- **July 27, 2005 -- An overview of current technology practices among the organizations represented by Subcommittee members**

    - *Barbara Baldwin, UVA Health Systems*

UVA Health Systems began using an electronic physician order entry system for in-patients 19 years ago. UVA recently concluded a 3-year RFP process to procure an electronic physician order entry system for out-patients. Implementation of that system is underway for out-patients and will eventually replace the older in-patient technology. Most physicians have familiarity with electronic systems through scheduling, billing, and possibly ordering. Consequently, a best practice identified at UVA is training physicians on how to use the systems and educating them on the benefits of such use, even though it may add non-billable "administrative time" to their work days. Challenges include dealing with different points of data entry (all of which collectively comprise the total electronic health record for an individual patient) and the ability to share information securely among the various UVA Medical Center facilities located throughout the Charlottesville area.

    - *Jeff Burke, Bon Secours Health Systems*

Teaching physicians the benefits of EHR is also a best practice identified in the Bon Secours Health System. Currently, physicians are being provided remote access to the Bon Secours network through virtual private networks (VPNs). Medical information is available online at all Bon Secours campuses. This includes physician reports, emergency department records, nursing assessments, vital signs, pharmacy orders, and demographic information in textual form and images of cardiology tests and physician orders. Medication administration in textual form is currently being implemented as are radiology images. The images are very

legible via the Web but are not quite "diagnostic quality." A major challenge is to keep all the data elements properly indexed to the right patient which is key for interoperability. A common vendor solution may provide greater interoperability but less functionality versus a niche technology solution which provides maximum functionality but little or no interoperability.

- *Tom Hanes, Sands Anderson Marks Miller*

In pouring through countless boxes of hardcopy medical records in the context of defending medical malpractice lawsuits, there is a tremendous amount of duplication of documents and services. As a result, it is very difficult to get an understanding of the total spectrum of patient care provided.

- *David Hollins, Hospital Corporation of America (HCA)*

HCA chose Meditech as its common EHR vendor to provide interoperability between HCA's nationwide facilities and campuses. Because HCA wanted interoperability, they gave up "best of breed" technology solutions. At this time, HCA does not have a true end-to-end electronic medical record system in any of its hospitals and is just beginning to implement an electronic physician order entry system. Physicians have remote access to the HCA network through virtual private networks (VPNs) using security fobs.

- *Rick Mears, Owens and Minor*

As a nationwide supplier of medical products and supplies, Owens and Minor has become very good at interoperability issues. The company helps to drive IT standards everyday and shows its customers how to leverage their data. From a supply chain view, EHR will help complete a feedback loop back to manufacturers and developers of medical products and supplies.

NOTE: Throughout these presentations, the subcommittee identified funding as a major challenge to EHR. Funding includes initial system implementation and training plus ongoing maintenance and upgrades. In the banking industry, 6% of the operating budget is the average spent on IT. In the health care industry, the average is 2% of the operating budget for IT. As a result, large hospital systems and stand-alone single hospitals have common challenges around funding EHR. Many stand-alone single hospitals are still doing everything on paper and may fall farther behind larger hospital systems in implementation of EHR if financial incentives are not provided.

- *Stephen Farmer, Anthem Southeast, Inc.*

Stephen Farmer provided the subcommittee with an understanding of the regulatory framework in which EHR must be developed. The top-tier regulating body is the U.S. Department of Health and Human Services (HHS), which is empowered by legislation to set and enforce regulations. The NHII resides in HHS. HHS also established the Centers for Medicare and Medicaid Services. The next tier is designated standards maintenance organizations (DSMO's), which are standard-setting organizations designated by HHS in its regulations to

maintain standards for the industry. Some DSMO's deal with the form of the standards. Two of many examples include the Accredited Standards Committee X-12 committee for electronic data interchange of financial and claims information and the Health Level Seven committee for clinical and administrative data (e.g., standardized data elements for EHR). Other committees deal with the data content of the standards. The final tier is other organizations of influence and importance such as the American Medical Association and the American Hospital Association. Groups in all of the tiers influence EHR in some way.

- **August 19, 2005 -- Interoperability and select best practices case study presentations**

In lieu of vendor presentations, the subcommittee requested presentations from various state and local agencies that are known as best practices case studies in EHR. Among the suggestions were Santa Barbara, California; Massachusetts; Indiana; the U.S. military; and Senior Navigator.

- *Katherine Gianola, M.D. – Connecting V.A. Hospitals with VISTA*

VISTA is a free computerized records management system that is currently being utilized within a network of eight V.A. hospitals. The system itself, which was demonstrated through a live connection to a hospital, includes several modules. The physician can document and include in the system a patient's vital signs within particular timeframes, inter-facility consults, medications dispensed and the results of laboratory tests. In addition, the system creates a variety of alerts; one such alert notifies physicians when there is a patient allergy, for example. The system can be used to order medications using an internal pharmacy. These orders are automatically sent to the internal pharmacies or lab. The system can be accessed from any remote location via VISTAweb.

Positive impacts as a result of system implementation include: enhanced patient safety, order checks and alerts, legibility, accountability and timeliness, concurrent provider chart use, better continuity of patient care, decreased verbal order usage, enhanced provider satisfaction and improved medical record documentation.

Lessons learned and tools for successful implementation include: a staged deployment, use a GUI format, seek out super-users and champions, encourage clinical application coordination (nurses and pharmacies), implement a very strong security program and have standing committees in place to address issues as they arise. Finally, it is essential to develop a backup system and have contingencies in place so that patient care is not compromised.

Questions/Comments:

1. How is data from other systems brought into VISTA? DOD records are currently available. Some data is scanned into the system.
2. Are there any arrangements with external pharmacies? Most orders are filled through internal pharmacies.
3. How many FTE's are supporting the system? There are approximately 2200 end-users and there are 4 FTE's supporting the system. There are other people who provide some support

but have other responsibilities. It is important to have a full-time Information Security Officer in place.
4. Is voice recognition software used at all? This has been tried but did not work out due to ambient noise within hospitals.
5. How much training would be required for doctors who have never seen the system? There is a very short learning curve; end-users received approximately 4 hours of training with periodic updates as needed.
6. Is billing included? Not yet. There are however, third party vendors who will provide this service.

- *James Lapsley, CEO, Loudon Medical Group, PC -- Connecting Providers Across Northern Virginia with AllScripts*

Loudon Medical Group began their electronic medical records implementation two years ago across fifty locations through a wide area network. The first priority was to eliminate charts and as much paper processing as possible. Putting an electronic medical records system in place is a huge undertaking and is an even larger cultural change for physicians. This must be managed throughout implementation. The decision was made here to implement the entire medical records system by location before moving onto another location. There should be an interface with billing and accounts receivable, however this interface is not easy.

Prior to implementation, Loudon Medical Group spent two years evaluating EMR's. There are many products available in the market today. AllScripts was the system Loudon settled on. Once a system is selected, it is essential to engage physicians in the planning process as best as possible. Having physicians sit on steering committees has been helpful. The return on investment on this project is not favorable. This will cost the Loudon Medical Group revenue due to the fact that physicians are not able to see as many patients; however they are hopeful that this will last only through the phased implementation period. The use of the EMR will not reduce staff either due to the fact that there will be staff needed to scan in patient information that is not available electronically. The implementation process for any EMR is slow and involves a major cultural change.

The main challenges for the Loudon Medical Group include trying to choose from so many different products, implementation and training.

Questions/Comments:

1. Is there any plan to interface with labs or other hospitals throughout the area? This is extremely expensive; around $30-40K per interface.
2. What about disaster recovery? Loudon Medical Group contracted with a vendor who provides a server farm for backup purposes. There is T1 redundancy as well.
3. Any suggestions to cope with cultural issues? Engage physicians early in the process. Take the time to choose the right product. Offer incentives.

- *Katie Roeper – Connecting Virginia Seniors to Services through a UAI*

Senior Navigator is a nonprofit organization that provides information services to Senior citizens. A database of senior services is provided and is accessible through a website. There is also a community component offered that does not include technology. Senior Navigator is working with Virginia to provide services to seniors through a universal assessment instrument. This is part of the "No Wrong Door" program endorsed by Virginia. Secretary Jane Woods has pulled together a committee to oversee the project. The committee consists of representatives from many Agencies across Virginia. There are currently three pilot projects underway – Peninsula Area, Greater Richmond Area and the Shenandoah Area. The committee is currently working on ways to deliver services to seniors, however there is interest in sharing information between EMR's and Senior Navigator.

Questions/Comments:

1. Any plans to move the program to the western part of the state? Already identifying other communities to roll this out.
2. What is used as the patient's unique identifier? Enter the patient's name and social security number and the system returns a unique identifier.

- *Dr. William Braithwaite – Interoperability from a National Perspective*

In looking at the three presentations already given, it is interesting to consider how interoperability could be achieved. Interoperability is critical for the success of any EMR. According to HL7, the definition of interoperability is "to exchange information and utilize information in ways that are accurate and verifiable when and where needed." This is not a clear or simple concept. Asking systems to exchange information when there is no connection is almost impossible.

In order to achieve interoperability, there are several qualities that need to be in place. These include:

- Trust – Must come to an agreement or contract where different organizations agree to share information in certain ways and to certain degrees.
- Finances – How will the exchange of information be financed? Who will pay for what?
- Technical standards – Must agree on standards, formats, and structures. HL7 serves as a basis for this. By next August, the HL7 group will release a standard method to move data across systems.

Finally, as stated, connecting across systems is a huge problem. The standards released by the HL7 group is a good format for this committee to use.

- *Dr. James Burns – Report from Association of State and Territory Health Officials*

A conference call was recently held with the members of the Association of State and Territory Health Officials (ASTHO). There were several states represented. They reported the following including Indiana, Minnesota, Rhode Island, Utah, Kentucky, New Hampshire, Pennsylvania, Virginia and Wisconsin:

- Indiana – 2 regional health information organizations (RHIOs) have been formed.
- Minnesota – There is an e-Health Steering Committee in place. The priority areas in which to share information are medications, communicable diseases, and laboratory results.
- Rhode Island – The AHRQ project is trying to establish interoperability across the state through the use of a master patient index.
- Utah – the Utah Health Information Network is in place. One hundred percent of hospitals use this for claims while 90% of physician the network for claims.
- New Hampshire – Community health centers use the same EMR; partnering with Medicaid to look at data sharing.
- Wisconsin – An estimated 35% of practices have an EMR.

In summary, everyone is struggling; there are no easy answers; developing a system takes a long time; and an EMR is expensive, so funding needs to be in place.

- **September 9, 2005 -- Privacy, security, governance, policy, and legal issues**

Staff commented that they have been trying to find common threads throughout the prior meetings in anticipation of compiling a draft report from Subcommittee # 4. It appears that nothing in the Code of Virginia is an impediment to producing an electronic health record. A question was asked regarding this: If there is nothing in the Code of Virginia to slow things down, is there anything that could help speed things up? For example, are electronic signatures legal? Currently, physicians can fax prescriptions to pharmacists, but they cannot send a prescription electronically with an electronic signature. Staff reported that the Code gives electronic signatures the same legal effect as traditional "wet" signatures. (See Title 1 of the Code of Virginia, section 1-13.32 and Title 59.1 of the Code of Virginia, section 59.1-501.7.) It was suggested that the regulations of the Boards of Medicine and Pharmacy should be encouraging the use of electronic health records and electronic signatures.

It has been suggested that legislation which relieves physicians of malpractice from using an electronic health record could be introduced. Why would using an electronic health record be an issue in court? The subcommittee concluded that this should only be an issue if the record were incorrect or erroneous, which could also happen with paper records. An example was cited where a physician receives an incorrect electronic health record and makes an incorrect diagnosis. It was recommended that a closer look be taken at how the Code addresses this through plaintiff and defense bar associations.

Regarding governance, the subcommittee expressed an interest in what other states are saying about the role of government within electronic health records. The word "governance" itself is tricky when it comes to describing the involvement of government, quasi-government, and private entities. Whatever "governance" may mean in this context, it involves the early involvement of key stakeholders and multi-disciplines. Any form of governance should represent the population.

In order to move forward with EHR in Virginia, it was noted that we should focus on some specific benchmarks, targets, and performance measures. We seem to be working from a high level perspective, so we need to translate this to more specifics. There are pilot projects being recommended within other subcommittees. Delegate O'Bannon discussed his suggestion to develop a pilot project that connects all the emergency departments in the Richmond metropolitan area. Since patient care would be directly affected in this pilot, the project would be something tangible by which to collect benchmark data. It is desirable to perhaps get all three large health provider systems (VCU/MCV, Bon Secours, and Henrico Doctors) in the metropolitan area to agree to share electronic health data. Physicians need to know that a patient has been to another emergency room for treatment before a diagnosis is made at a different hospital.

In order to move forward into something more tangible, it was noted that we must look at the concept of the master patient index. Most subcommittee members agreed that it would be difficult to move forward without developing this. The Virginia Department of Health currently uses a master patient index of some kind to collect bioterrorism information in the NOVA region through a project known as ESSENCE II. The Health Department also collects immunization information.

Concerning the master patient index, it was noted that it probably would not be a good idea to use social security numbers for this, nor would it be desirable to assign a number to every citizen in Virginia. Instead of assigning numbers, would there be ways to use technology to manage this process? Creating the master patient index also becomes an infrastructure issue that needs to be addressed. It was agreed that Subcommittee # 4 might be able to recommend ways to form a master patient index. In order to develop the data elements for the master patient index, it might be helpful to match these with the Centers for Medicare and Medicaid Services (CMS). CMS defines key data elements and provides financial incentives if targets are hit. It might also be helpful to look at what the Health Department is doing with ESSENCE II. However this is accomplished, it was agreed that a repository of patient clinical results should not be centralized. Placing all this information in one centralized database is not desirable for many reasons, including security, redundancy, privacy, and accessibility. However, the subcommittee recognized the need to have a central broker for the master patient index and discussed whether the Virginia Department of Health could serve in this role.

Regarding security, the subcommittee felt that there should not be a problem with the Health Insurance Portability and Accountability Act of 1996 (HIPPA) in the creation of an EHR system as long as entities understand how information is exchanged and everyone agrees. HIPAA sets privacy and security standards and addresses business continuity but not necessarily redundancy.

To move forward with EHR in Virginia, how do we overcome the barrier of dollars for investment in this process? The federal government has focused on regional health information organizations (RHIOs). Some members of the Task Force seem to agree that RHIOs are the place to start since this is where the federal government is currently focusing money. Others disagree and indicate that forming a RHIO "puts the cart before the horse" by

creating a clearinghouse mechanism to exchange electronic health records before encouraging the creation of EHR in the first place. It was stated that if a RHIO is formed in Virginia, it could be the keeper of the master index while the patient information itself remains decentralized.

- **Findings and Recommendations -- Technology and Interoperability**

1. Terminology and data elements have been standardized by the National Health Information Infrastructure (NHII), an initiative of the U.S. Department of Health and Human Services. As a result, there is no need for Virginia's pilot projects to "reinvent the wheel" on many of the technology standards that could be adopted from NHII. Additional advantages to adopting NHII standards are that: (i) it would provide a framework upon which to continue to build a more complete health information system in the future and (ii) compliance with federal requirements as a prerequisite to future federal funding would be achieved.

2. The ability to share information about patients across various health provider systems is key to developing EHR in Virginia. The subcommittee does not recommend that the government issue a health identification number to every citizen; however, a master patient index should be retained at a centralized repository such as a regional health information office (RHIO) that contains enough standardized data elements to accurately identify patients. Records of individual patients should be maintained at decentralized facility locations. This is the model adopted by the Massachusetts Health Data Consortium.

3. In order to develop the data elements for the master patient index, it might be helpful to match these with the Centers for Medicare and Medicaid Services (CMS). CMS defines key data elements and provides financial incentives if targets are hit.

4. The project known as "Essence II" should also be studied carefully to identify best practices in sharing information about patients across various health provider systems and developing a master patient index. The Virginia Department of Health is actively collecting data from nearly 30 emergency rooms, mostly in Northern Virginia and Tidewater, and analyzing the data daily for suspicious patterns of disease and bioterrorist threat. Data is shared with health departments in Washington, D.C. and Maryland so that any pattern in the National Capitol Region can be detected. Essence II is a joint project with Johns Hopkins Advanced Physics Lab and the Defense Advanced Research Projects Agency.

- **Findings and Recommendations -- Privacy And Security**

5. Regulations issued by the federal Department of Health and Human Services (HHS) which implement the Health Insurance Portability and Accountability Act of 1996 (HIPPA) provide minimum acceptable standards for privacy and security of EHR. The standards apply to health information created or maintained by health care providers who engage in certain electronic transactions, health plans, and health care clearinghouses and

also address business system continuity and redundancy in the event of disasters such as Hurricane Katrina.

- **Findings and Recommendations – Governance, Policy, and Legal Issues**

6. Governance of EHR in Virginia should be provided by multi-disciplinary stakeholders from the private sector, government, and quasi-government entities and they should be involved early in the discussion of EHR. Focusing on early involvement by key stakeholders may help target important topics such as funding, incentives, and physician acceptance.

7. To provide initial benchmarks in EHR for emergency departments and electronic prescription systems and medication tracking, governance should be closely related to the performance measures and goals required by the Centers for Medicare and Medicaid Services (CMS). CMS provides financial incentives for attaining performance measures and goals.

8. The Code of Virginia should encourage use of EHR by relieving doctors and hospitals of medical malpractice claims for the mere sharing or reliance on EHR. In other words, sharing or reliance on EHR per se should not be considered negligence. Similar issues have been raised in the context of telemedicine, venue, and credentialing requirements.

9. The Boards of Medicine and Pharmacy should encourage use of EHR in their regulations, including the use of electronic signatures by physicians and pharmacists.

10. As part of its licensing regulations, the Virginia Department of Health should encourage the use of EHR by non-resident companies that own hospitals located in Virginia.

11. Identifying and eliminating legal and regulatory barriers at the federal level should be undertaken by the federal government, particularly for the 110,000 pages of Medicare regulations from the U.S. Department of Health and Human Services.

Members of Subcommittee #4

- Secretary Eugene Huang, chair
- Barbara Baldwin – UVA Health Systems
- Jeff Burke – Bon Secours Health Systems
- Carl Gattuso – VCU Health Systems
- Tom Hanes – Sands Anderson Marks Miller
- David Hollins – Hospital Corporation of America
- Rick Mears – Owens and Minor
- John O'Bannon – Neurologist and Member of the Virginia House of Delegates
- Becky Snead – Virginia Pharmacy Association

Subcommittee #4 Staff:

- Diane Horvath – Manager, Legal and Legislative Services, VITA
- Debbie Secor – Enterprise Service Director, Health and Human Services Secretariat, VITA